M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS

DATE: November 06, 2000

FROM: Gregg Davis
Chief, Regulatory Support Branch
Division of Labeling and Program Support

G Davis 07-NOV-2000

THROUGH: Peter Rickman
Acting Director, Division of Labeling and Program Support

SUBJECT: Statistical Report - Month of October, 2000

TO: See Below

This memorandum represents the Office of Generic Drugs' statistical report for October, 2000.

Tables I through III detail quantitative information about OGD's receipts, actions, and pending review status for both original and supplemental (CMC and labeling) applications for the past month and for the 11 preceding months. Following the tables, graphic presentations of selective quantitative data are provided. These graphs allow comparisons to similar data dating back to 1995. Where appropriate, the graphs have been modified to reflect the change of AADAs to ANDAs as a result of the elimination of Section 507 of the FD&C Act under FDAMA.

Approvals for the month of October include 21 new generic full approvals and 3 tentative approvals. Of the 24 approvals, 9 applications were approved as first generics. Separate lists of the approvals for the month of October follow the graphic presentations.

905-0308

M692

Center for Drug Evaluation and Research - Office of Generic Drugs

Table I

Quantitative Report

ORIGINAL APPLICATIONS

	Nov-99	Dec-99	Jan-00	Feb-00	Mar-00	Apr-00	May-00	Jun-00	Jul-00	Aug-00	Sep-00	Oct-00	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-- RECEIPTS --																
TOTAL ORIGINALS	17	46	19	24	20	18	48	38	19	22	47	20	338	28	30	27
AMENDMENTS	139	131	112	132	170	124	144	138	140	145	103	141	1619	135	130	129
- MAJOR	57	62	40	61	69	53	64	56	58	73	55	77	725	60	68	60
- MINOR	48	34	44	47	60	39	46	49	52	54	32	44	549	46	43	33
- FACSIMILE**	34	35	28	24	41	32	34	33	30	18	16	20	345	29	18	36
-- ACTIONS --																
APPROVALS	19	15	18	21	21	18	23	25	14	25	21	21	241	20	22	16
TENTATIVE APPROVALS+	3	2	3	5	9	10	5	5	6	3	3	3	57	5	3	6
NOT APPROVABLE	38	46	28	60	72	34	41	36	44	51	41	47	538	45	46	41
FACSIMILE REQUEST**	16	19	13	18	34	11	16	16	5	13	14	26	201	17	18	18
REFUSE TO RECEIVE	6	0	4	7	10	1	6	7	9	4	4	7	65	5	5	6
WITHDRAWALS	7	5	43	9	14	6	45	55	8	23	2	46	263	22	24	28
- OF APPROVED	3	3	37	4	11	3	14	22	1	19	0	45	162	14	21	21
- OF UNAPPROVED	4	2	6	5	3	3	31	33	7	4	2	1	101	8	2	8
-- REVIEW STATUS --																
AWAITING OGD ACTION (TOTAL)***	415	438	414	398	376	377	397	413	416	405	422	407		407	411	422
AWAITING OGD ACTION (> 180 DAYS)***	71	74	82	73	68	63	57	64	44	47	57	51		63	52	89
AWAITING OGD ACTION (<=180 DAYS)***	344	364	332	325	308	314	340	349	372	358	365	356		344	360	333

** Facsimile policy went into effect in January of 1997

*** In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. Review status figures reported since this date exclude suspended applications.

As of October 31, 2000, 1 original application and 9 supplements were suspended.

Upon completion of validity assessments, suspended applications may be returned to active pending status.

+ Note: Tentative approvals are counted as approvals subsequently when approved.

Center for Drug Evaluation and Research - Office of Generic Drugs

Table II

Quantitative Report

POST APPROVAL SUBMISSIONS TO APPLICATIONS (CHEMISTRY)

	Nov-99	Dec-99	Jan-00	Feb-00	Mar-00	Apr-00	May-00	Jun-00	Jul-00	Aug-00	Sep-00	Oct-00	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	161	116	173	297	166	152	156	224	276	240	182	181	2324	194	201	203
AMENDMENTS TO SUPPLEMENTS	198	200	242	579	293	229	205	295	337	292	222	214	3306	276	243	214
--SUPPLEMENTAL ACTIONS-- **																
APPROVALS	176	185	216	143	201	189	334	112	268	167	136	169	2296	191	157	186
APPROVABLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOT APPROVABLE	42	98	136	109	128	32	96	92	56	70	115	76	1050	88	87	111
WITHDRAWALS	18	19	27	6	69	17	35	13	26	18	16	74	338	28	36	22
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL) *	1331	1257	1119	1353	1223	1242	1058	1094	1104	1183	1189	1188		1195	1187	1498
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	156	178	156	188	132	87	54	102	84	124	84	92		120	100	154
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	1175	1079	963	1165	1091	1155	1004	992	1020	1059	1105	1096		1075	1087	1345

* In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. Review status figures reported since this date exclude suspended applications.
As of October 31, 2000, 1 original application and 9 supplements were suspended.
Upon completion of validity assessments, suspended applications may be returned to active pending status.

** Supplemental actions between May 1999 and April 2000 had previously been underreported due to an electronic report error.

Center for Drug Evaluation and Research - Office of Generic Drugs

Quantitative Report

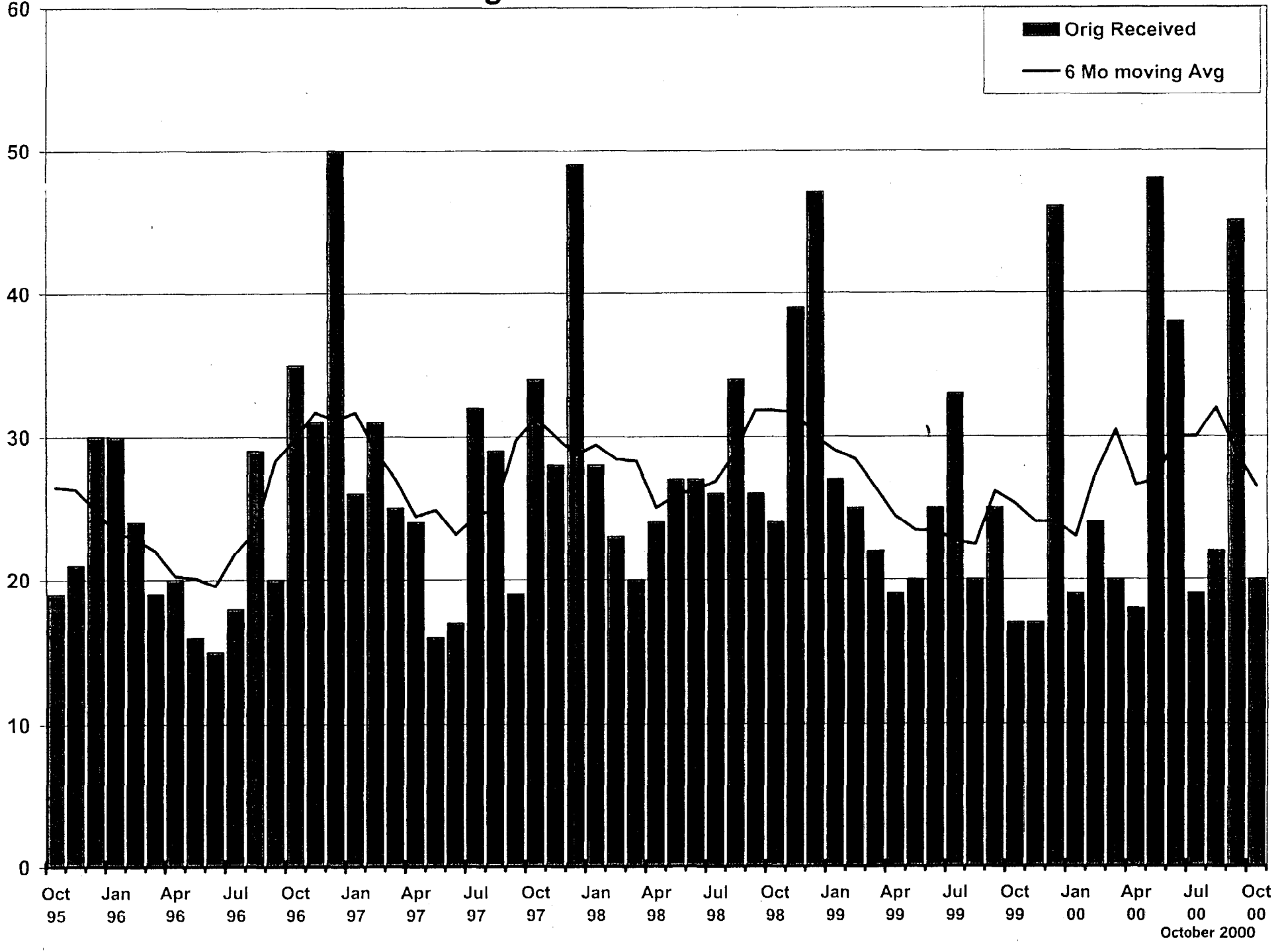
Table III

POST APPROVAL SUBMISSIONS TO APPLICATIONS (LABELING)

	Nov-99	Dec-99	Jan-00	Feb-00	Mar-00	Apr-00	May-00	Jun-00	Jul-00	Aug-00	Sep-00	Oct-00	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
–RECEIPTS–																
ORIGINAL SUPPLEMENTS	45	25	22	47	43	35	46	24	64	62	60	58	531	44	60	46
AMENDMENTS TO SUPPLEMENTS	39	61	31	53	64	46	55	45	80	67	63	64	668	56	65	60
–SUPPLEMENTAL ACTIONS–																
APPROVALS	75	42	40	38	43	35	27	22	36	72	51	77	558	47	67	46
APPROVABLE	13	3	4	12	2	13	4	1	3	5	2	5	67	6	4	7
NOT APPROVABLE	23	8	9	7	11	11	13	24	4	9	11	11	141	12	10	16
WITHDRAWALS	5	0	0	0	1	1	0	8	3	1	4	2	25	2	2	5
–REVIEW STATUS–																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL)	218	229	205	213	215	214	224	224	265	253	261	240		230	251	304
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	81	86	83	83	77	80	87	83	82	85	83	94		84	87	111
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	137	143	122	130	138	134	137	141	183	168	178	146		146	164	194

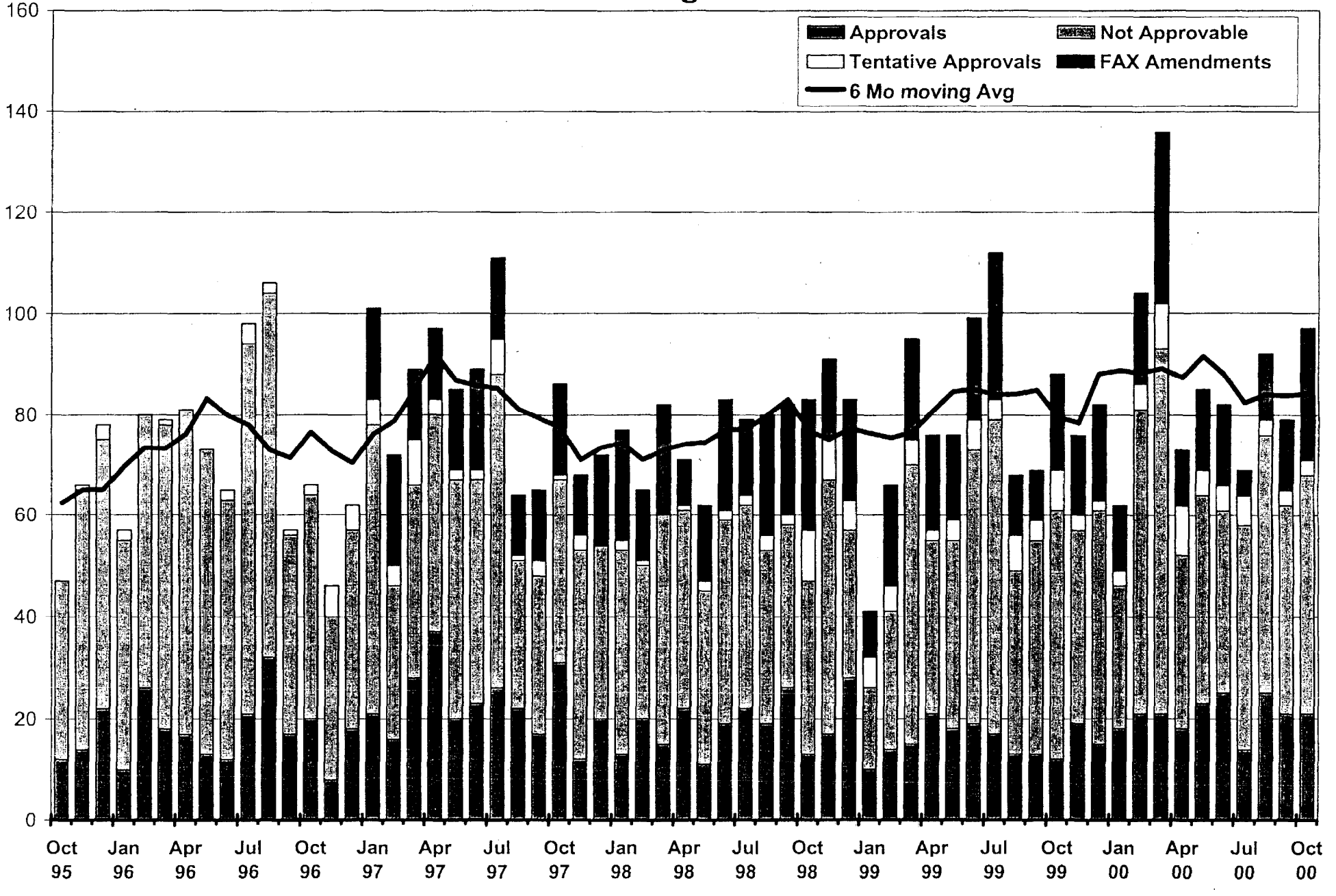
* In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. Review status figures reported since this date exclude suspended applications.
As of October 31, 2000, 1 original application and 9 supplements were suspended.
Upon completion of validity assessments, suspended applications may be returned to active pending status.

Original ANDAs Received



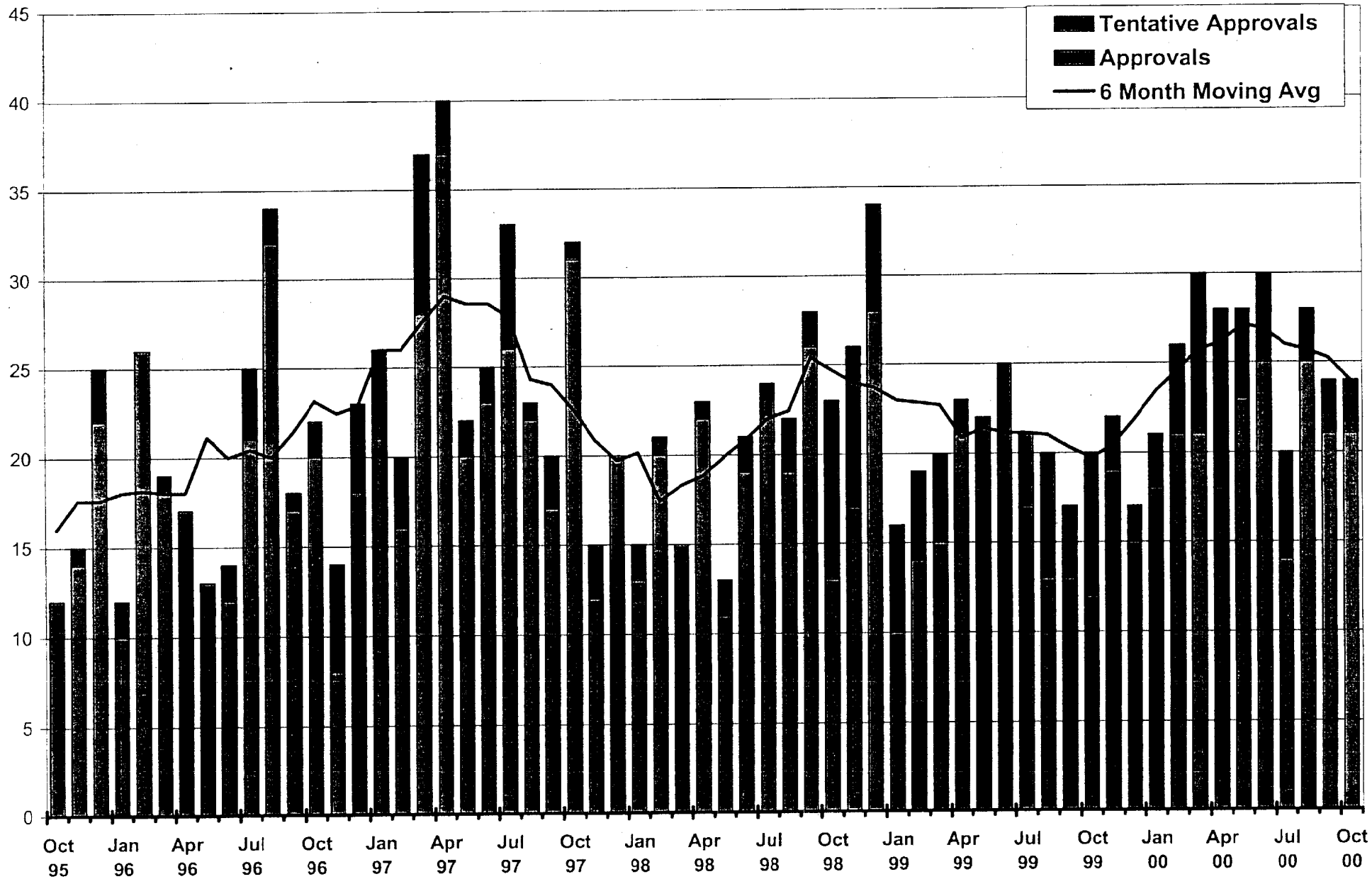
October 2000

Actions on Original ANDAs



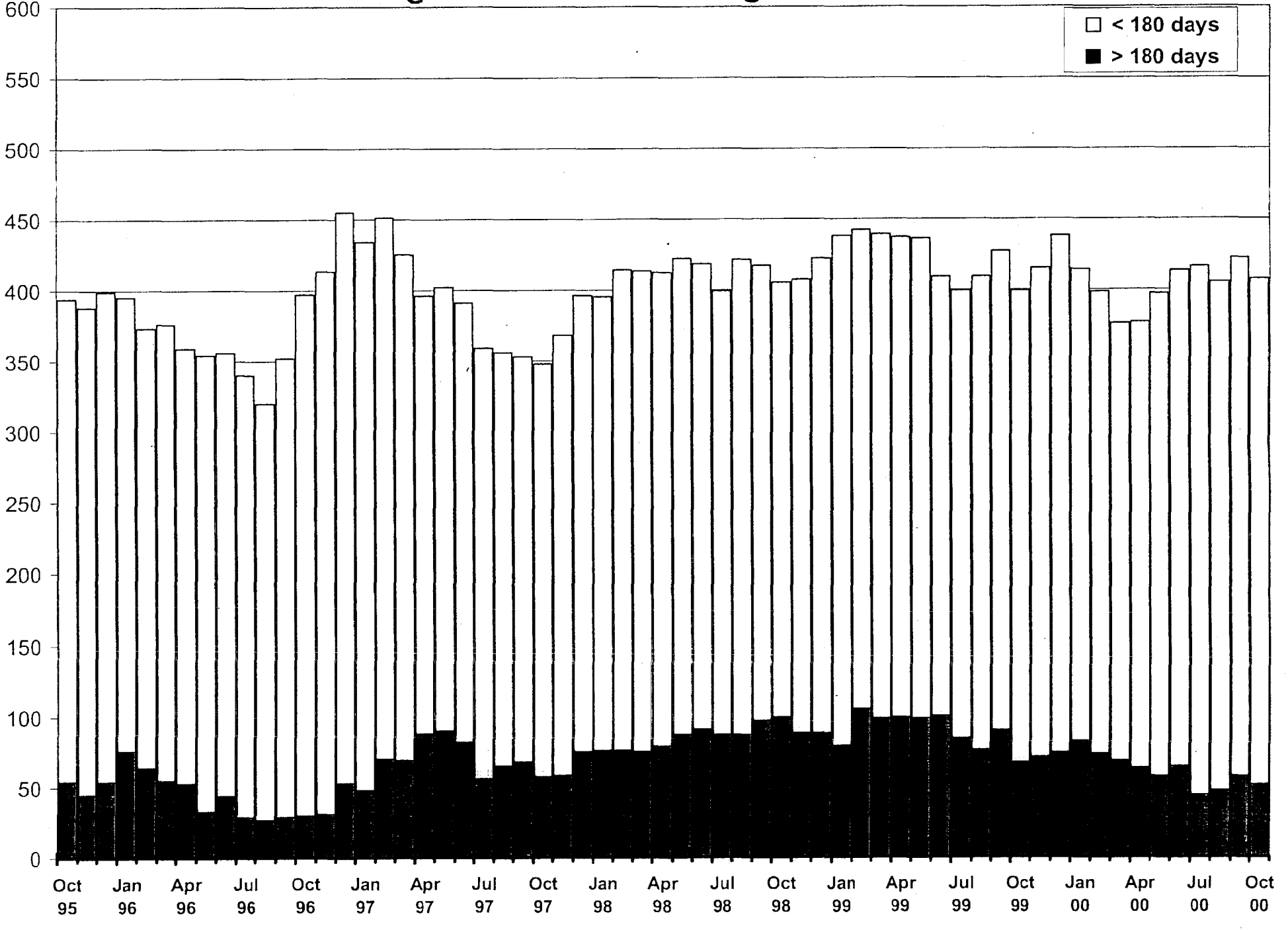
Note: Tentative Approvals (TA) are applications that have been approved by the office pending patent expiration. TAs are counted as approvals subsequently when approved. For example, 44 of 66 approvals for Feb 1996 were previously TA'd. The large number of approvals resulted from a drug coming off patent in February.

Original ANDAs Approved or Tentatively Approved

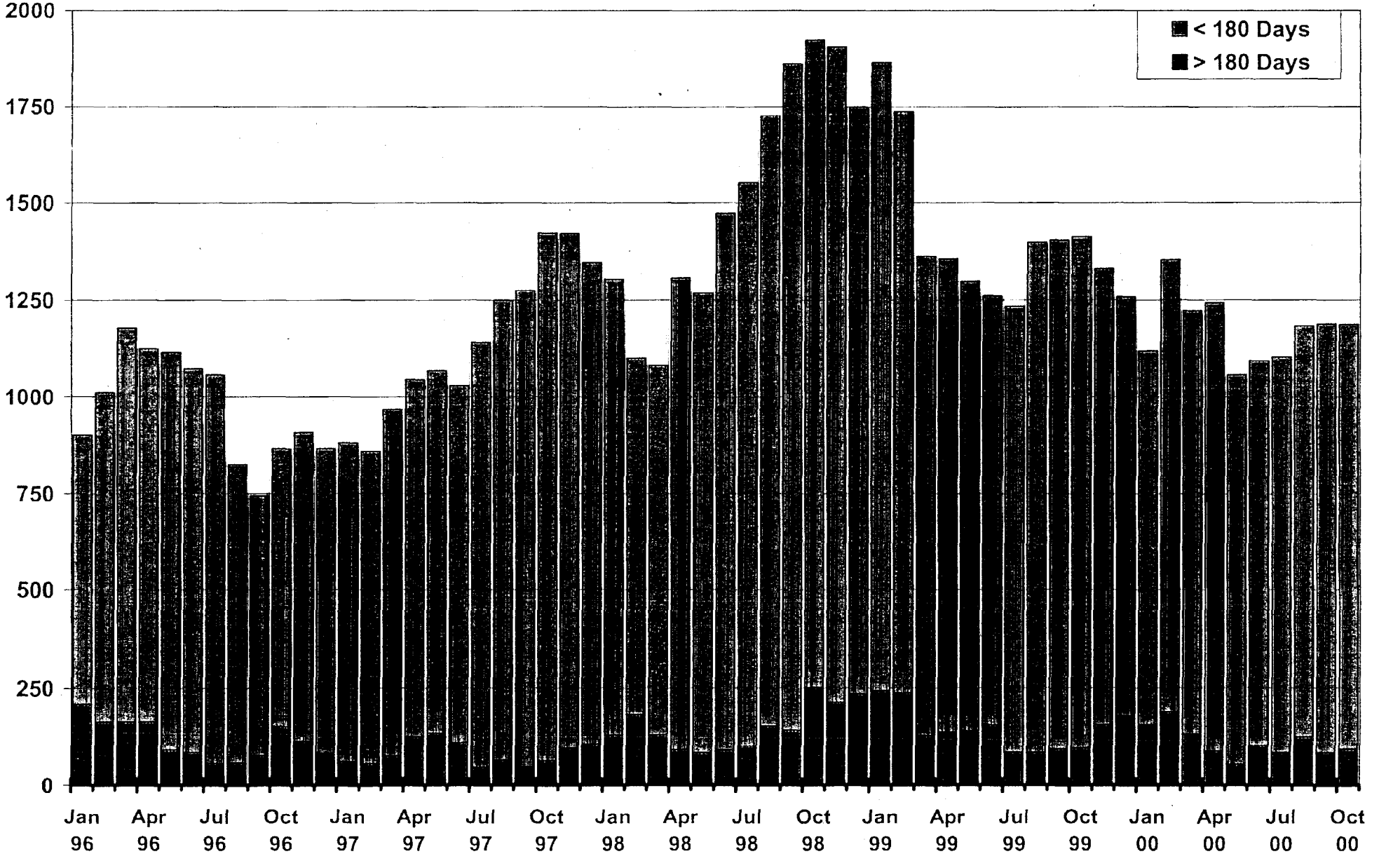


Note: Tentative Approvals (TA) are applications that have been approved by the office pending patent expiration. TAs are counted as approvals subsequently when approved. For example, 44 of 66 approvals for Feb 1996 were previously TA'd. The large number of approvals resulted from a drug coming off patent in February.

Original ANDAs Pending Per Month

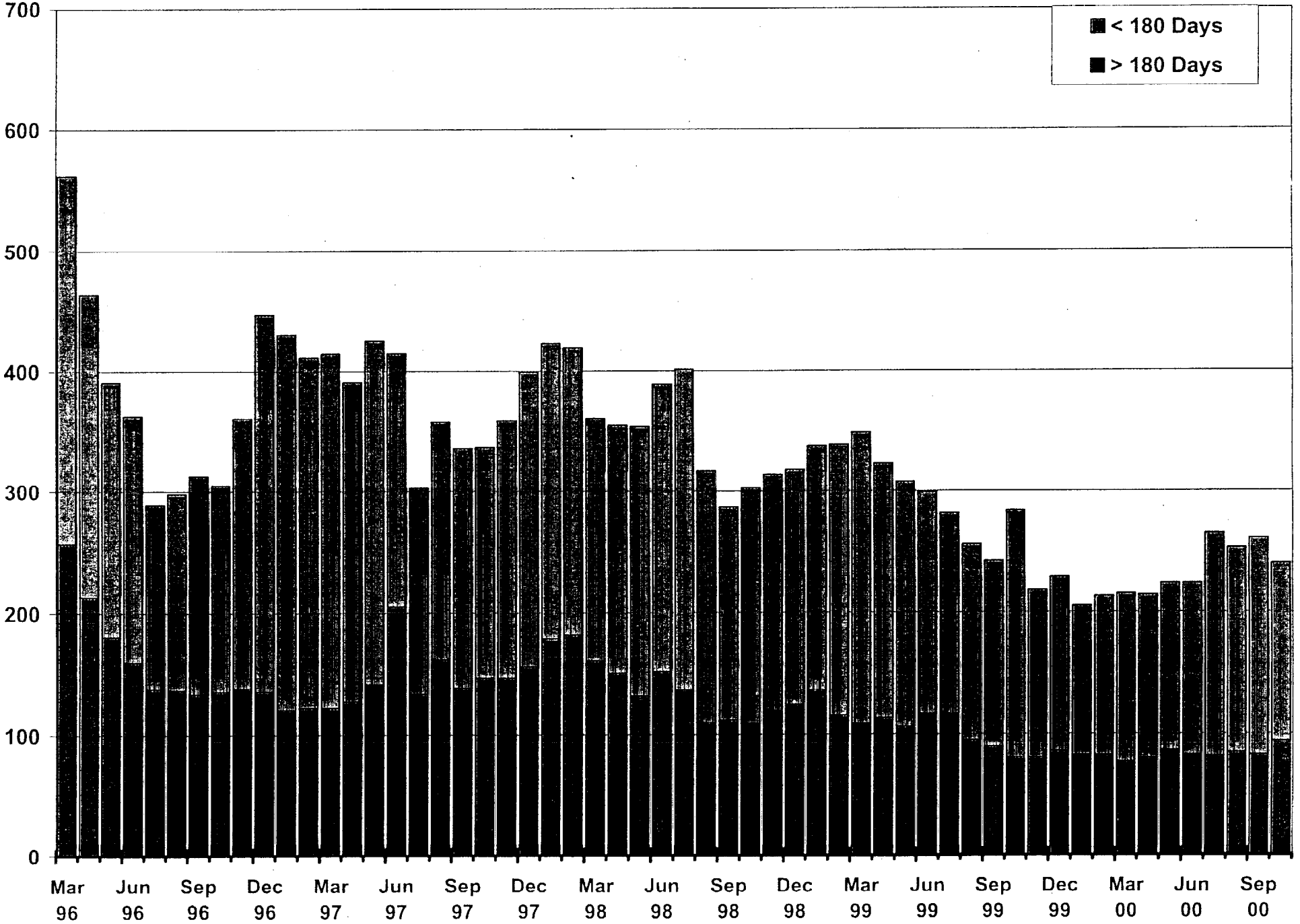


Chemistry, Manufacturing & Controls Supplements Awaiting OGD Action

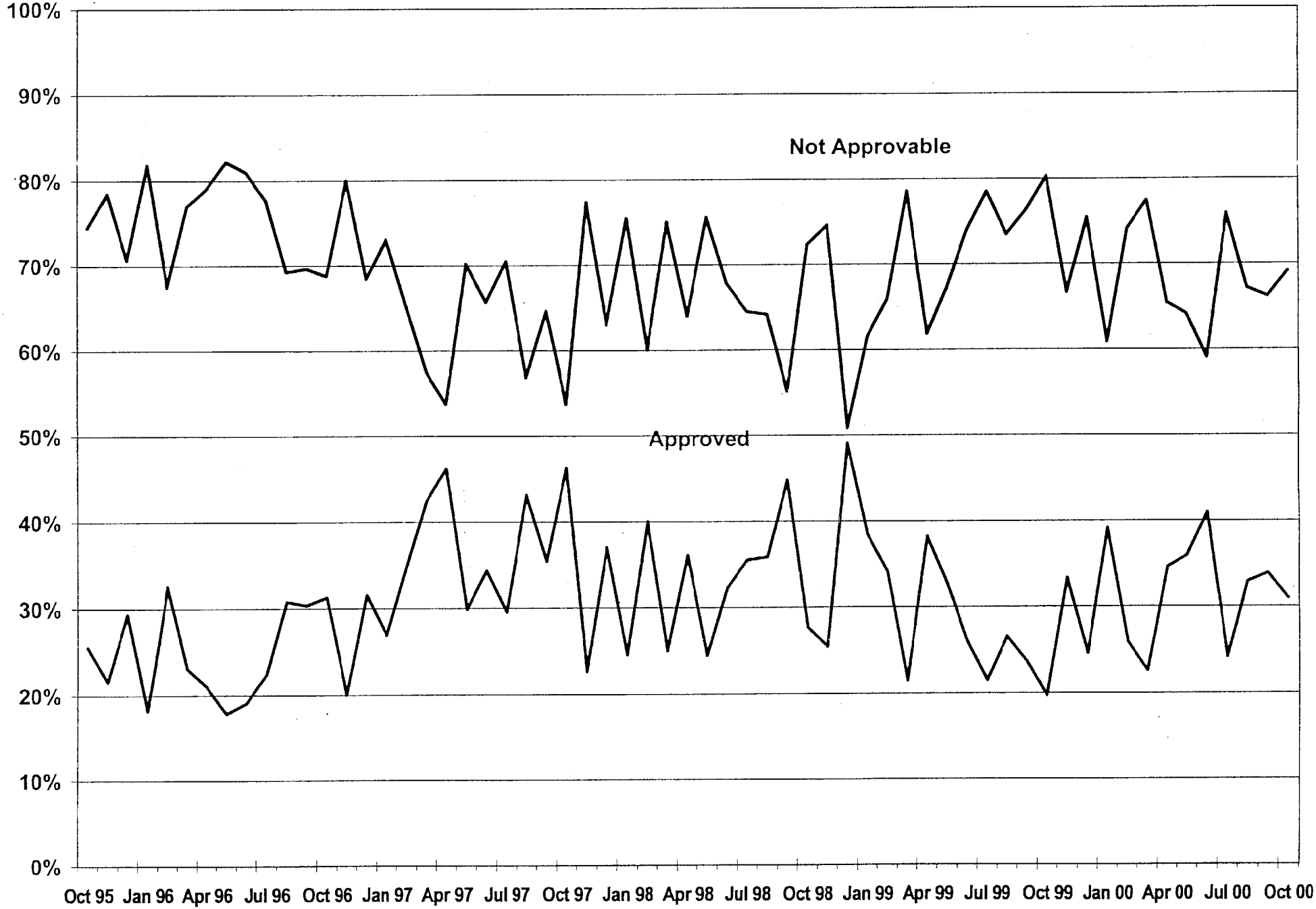


Please note that abrupt changes in the level of pending supplements (e.g., the increase in October 1998) are the result of global submissions to all applications held by a single firm. Changes other than these will be explained separately.

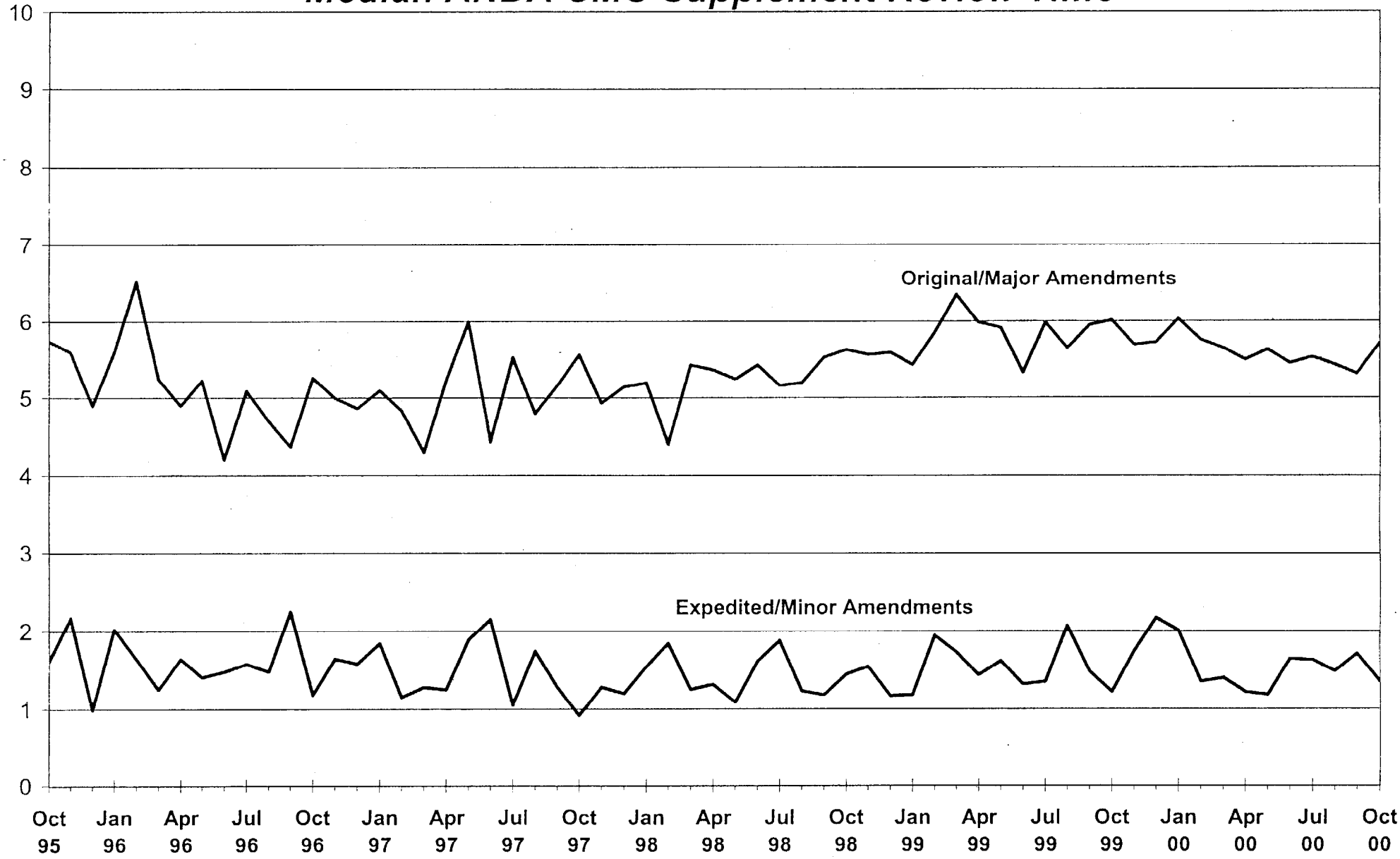
Labeling Supplements Awaiting OGD Action



Percent Approved and Not-Approvable By Month



Median ANDA CMC Supplement Review Time

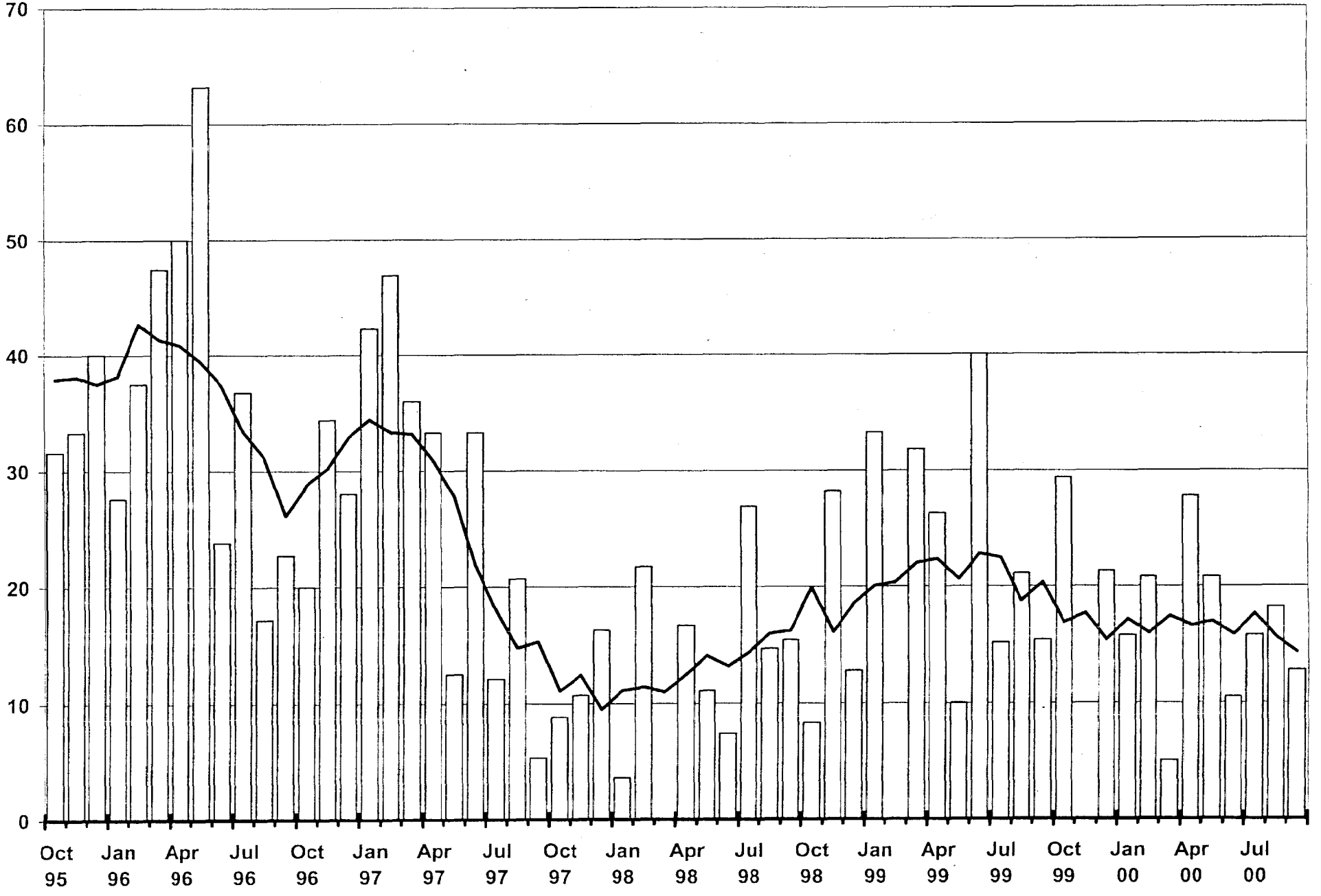


1 - Times correspond to actual applications received. The new ANDA/AADA submission policy that went into effect 1/1/91 allows certain variations in a drug product to be included in a single application.

2 - In September 1991, the OGD started implementation of the Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. AIP time has been subtracted from review time above for the period after 9/91. However, before the AIP went into effect, the review of many applications suspected of containing fraudulent data were suspended. These suspensions were not recorded in the MIS and are reflected in the above chart.

3 - Global Supplements are Collapsed

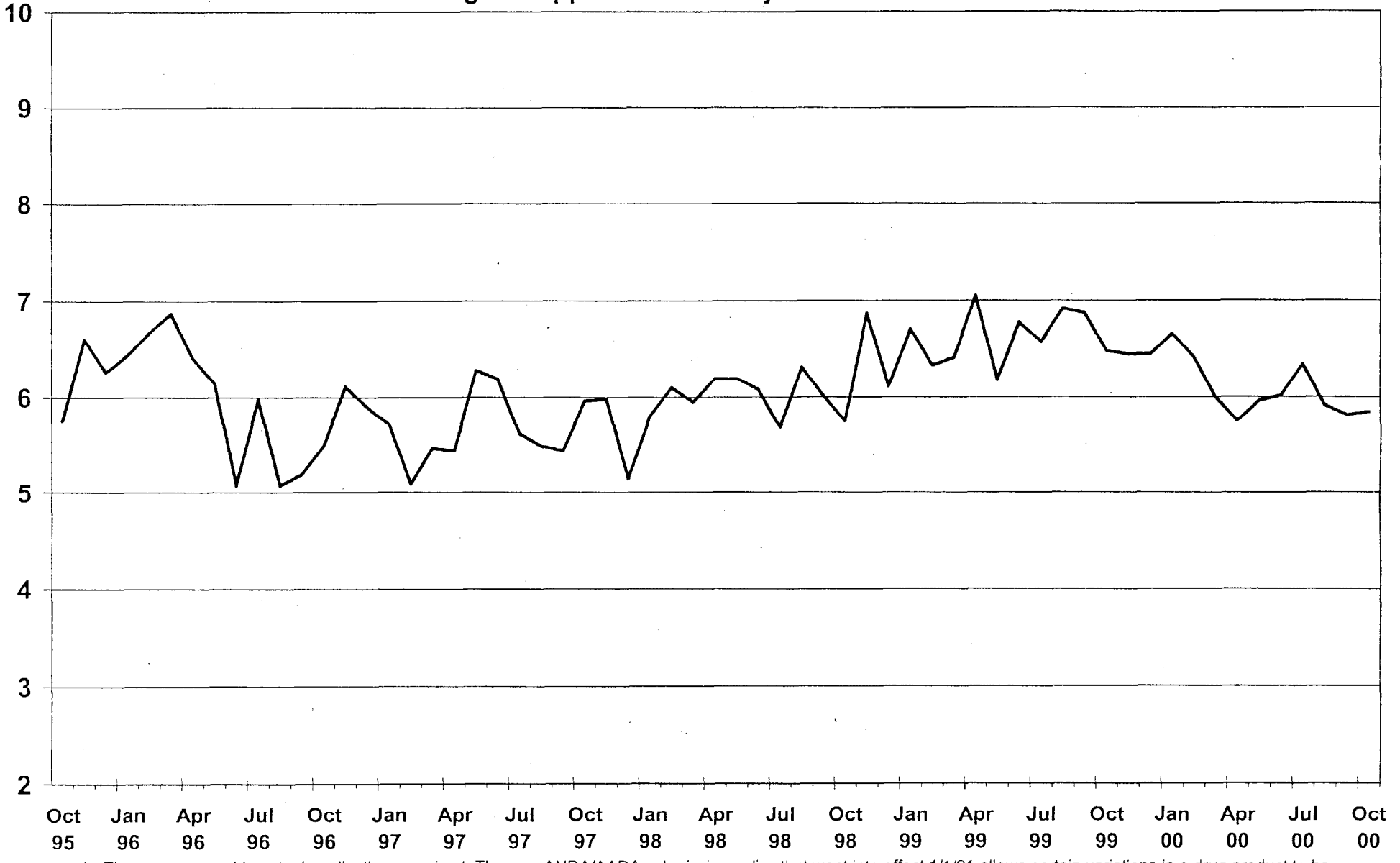
Percent of Original Submissions with Refuse to Receive Action



Status as of October 31, 2000. Percentages for recent months may increase due to future R/R actions

Median ANDA Review Cycle (Months)

Original Applications & Major Amendments



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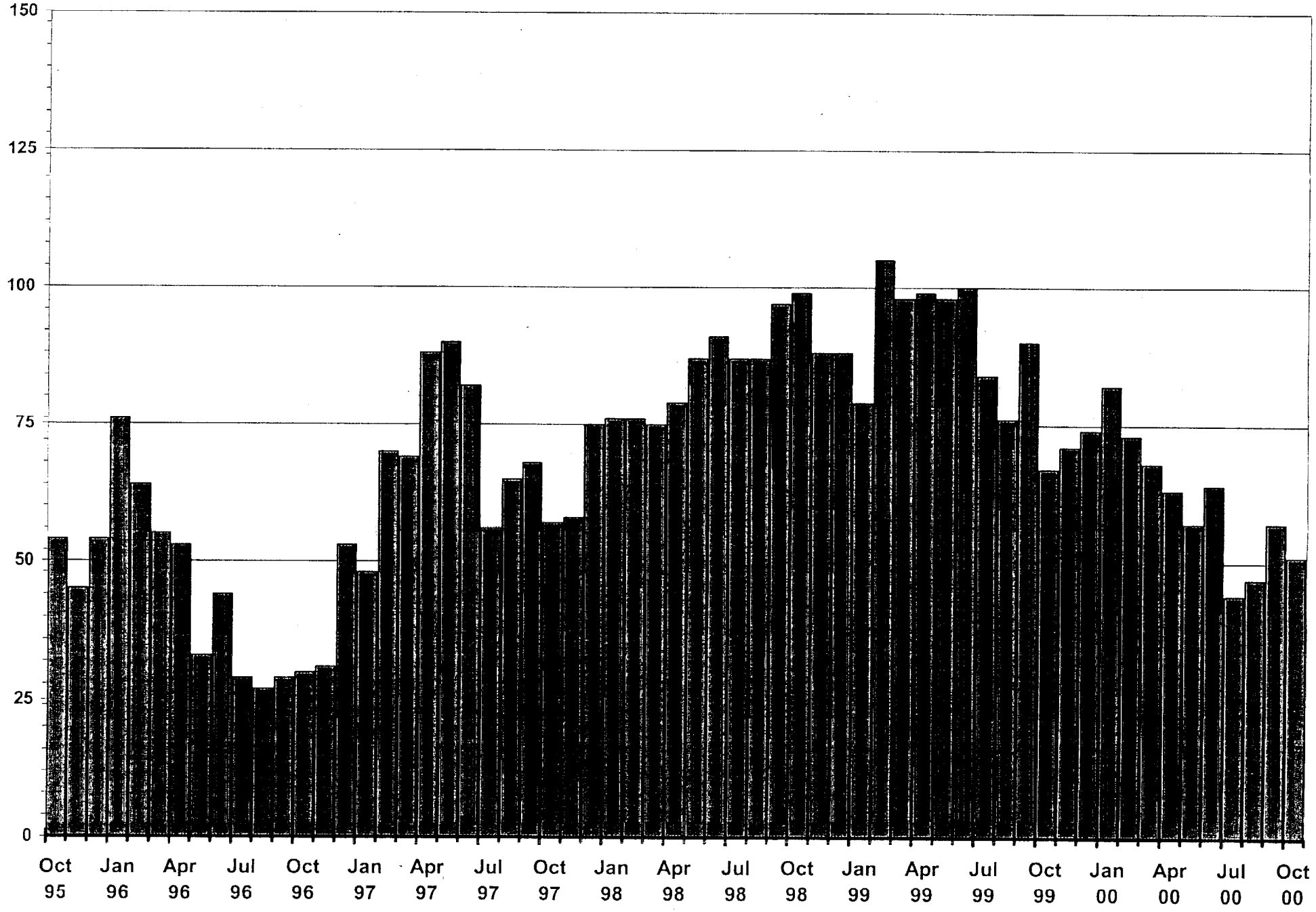
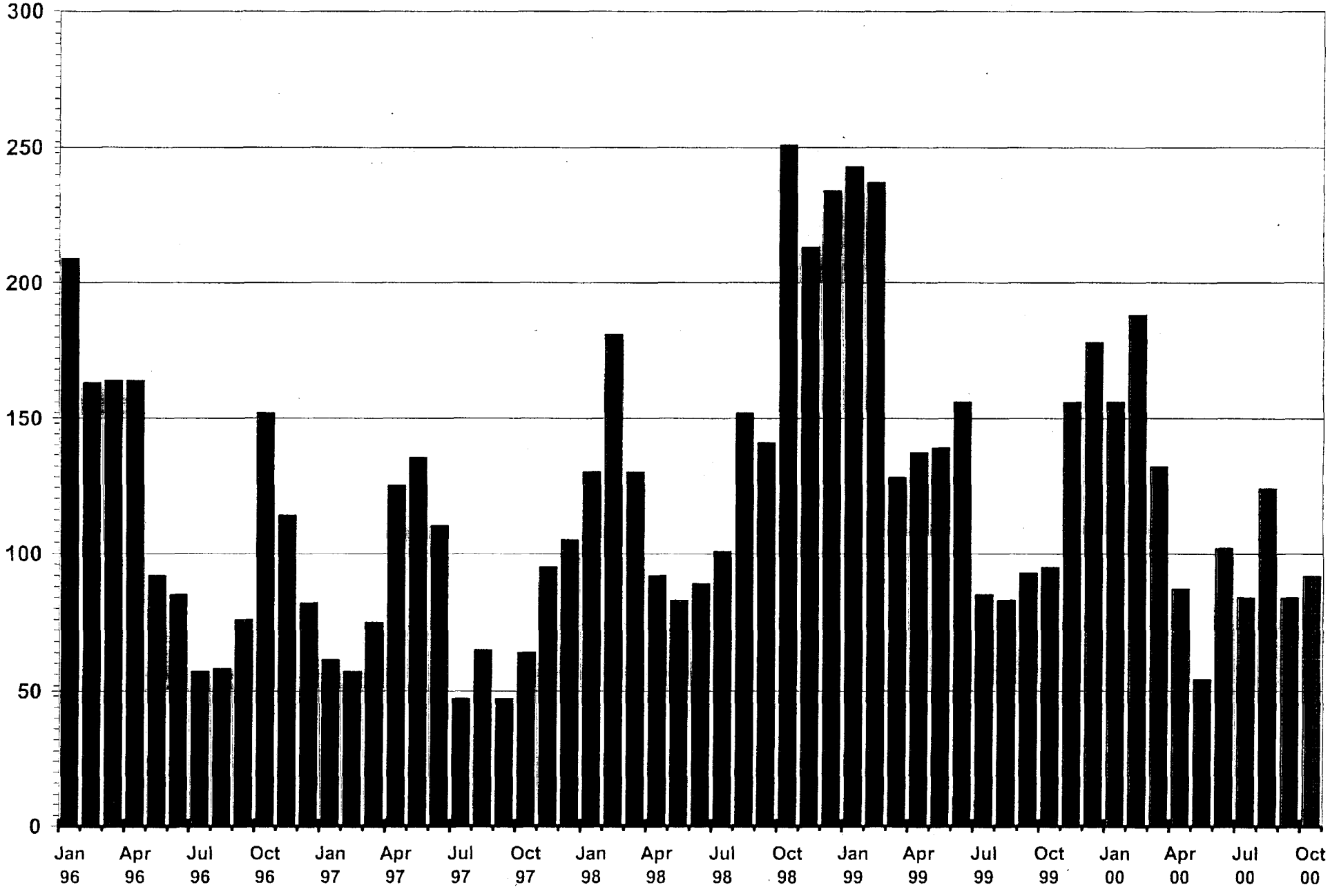
Original ANDAs Pending > 180 Days



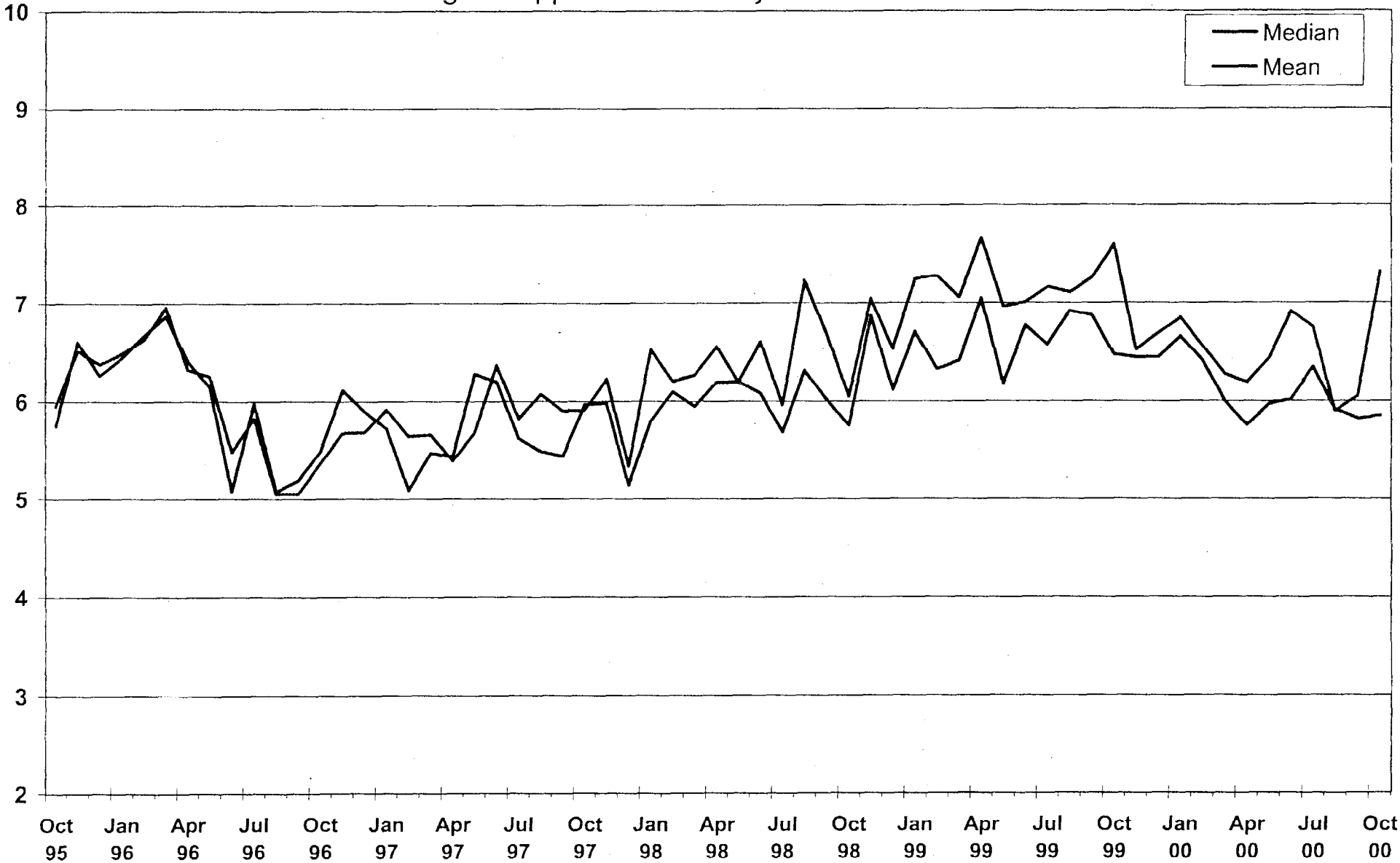
ANDAs CMC Supplements Pending > 180 Days



Please note that abrupt changes in the level of pending supplements (e.g., the increase in October 1998) are the result of global submissions to all applications held by a single firm. Changes other than these will be explained separately.

Mean and Median ANDA Review Cycle (Months)

Original Applications & Major Amendments



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Office Of Generic Drugs ANDAs Approvals October 2000

1 . 40-304	OXYCODONE AND ACETAMINOPHEN CAPSULES, USP 5 MG/500 MG	BARR LABORATORIES, INC.	10/2/00
2 . 75-361	ISOSORBIDE MONONITRATE TABLETS 20 MG	WESTWARD PHARMACEUTICAL CORP.	10/5/00
3 . 75-468	CLONAZEPAM TABLETS, USP 0.5 MG 1 MG 2 MG	TORPHARM	10/6/00
4 . 75-613	BUPROPION HYDROCHLORIDE TABLETS 75 MG 100 MG	EON LABS MANUFACTURING, INC.	10/10/00
5 . 75-426	DOXAZOSIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	CHELSEA LABORATORIES, INC.	10/18/00
6 . 75-432	DOXASOZIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	INVAMED INC.	10/18/00
7 . 75-453	DOXASOZIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	ZENITH GOLDLINE PHARMACEUTICALS, INC.	10/18/00
8 . 75-466	DOXASOZIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	GENPHARM, INC.	10/18/00
9 . 75-536	DOXAZOSIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	TEVA PHARMACEUTICALS USA	10/18/00
10 . 75-574	DOXAZOSIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	PUREPAC PHARMACEUTICAL CO.	10/18/00
11 . 75-580	DOXAZOSIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	TORPHARM	10/18/00

12 . 75-609	DOXASOZIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	KV PHARMACEUTICAL COMPANY	10/18/00
13 . 75-646	DOXAZOSIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	EON LABS MANUFACTURING, INC.	10/18/00
14 . 75-509	DOXASOZIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	MYLAN PHARMACEUTICALS, INC.	10/19/00
15 . 75-641	MIDAZOLAM HYDROCHLORIDE INJECTION 5 MG (BASE)/ML (2 ML SYRINGE)	APOTHECON INC.	10/19/00
16 . 40-409	HYDROCODONE BITARTRATE AND ACETAMINOPHEN TABLETS, USP 5 MG/325 MG	MALLINCKRODT, INC.	10/20/00
17 . 75-203	PROPAFENONE HYDROCHLORIDE TABLETS 150 MG 225 MG	WATSON LABORATORIES, INC.	10/24/00
18 . 75-687	CARBAMAZEPINE TABLETS, USP (CHEWABLE) 100 MG	TARO PHARMACEUTICAL INDUSTRIES, LTD.	10/24/00
19 . 75-471	LEUPROLIDE ACETATE INJECTION 1 MG/0.2 MG (MULTIPLE-DOSE VIAL)	GENSIA SICOR PHARMACEUTICALS, INC.	10/25/00
20 . 75-564	RANITIDINE CAPSULES 150 MG 300 MG	GENPHARM INC.	10/27/00
21 . 75-637	MIDAZOLAM HYDROCHLORIDE INJECTION 1 MG (BASE)/ML 5 MG (BASE)/ML	APOTEX CORP.	10/31/00

Office of Generic Drugs ANDAs Tentative Approvals October 2000

1 .	75-297	PACLITAXEL INJECTION 6 MG/ML	ZENITH GOLDLINE PHARMACEUTICALS, INC.	10/10/00
2 .	75-671	MEGESTROL ACETATE ORAL SUSPENSION 40 MG/ML	PAR PHARMACEUTICAL, INC.	10/23/00
3 .	75-616	NIZATIDINE CAPSULES, USP 150 MG 300 MG	DANBURY PHARMACAL, INC.	10/25/00

Office of Generic Drugs Approved Drugs Log - First Time

ANDA No.	*Established Name/Dosage Form and Stregnth*	*Applicant*	*SUB Date*	*Type*	*TA Date*	*AP Date*	*Innovator Co*	*Reference Drug*
75-671	MEGESTROL ACETATE ORAL SUSPENSION 40 MG/ML	PAR PHARMACEUTICAL, INC.	7/15/99	TA	10/23/00		BRISTOL MYERS SQUIBB	MEGACE ORAL SUSPENSION
75-466	DOXASOZIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	GENPHARM, INC.	9/28/98	AP		10/18/00	PFIZER LABORATORIES	CARDURA TABLETS
75-580	DOXAZOSIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	TORPHARM	2/12/99	AP		10/18/00	PFIZER LABORATORIES	CARDURA TABLETS
75-426	DOXAZOSIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	CHELSEA LABORATORIES,	8/3/98	AP		10/18/00	PFIZER LABORATORIES	CARDURA TABLETS
75-646	DOXAZOSIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	EON LABS MANUFACTURING,	6/10/99	AP		10/18/00	PFIZER LABORATORIES	CARDURA TABLETS
75-574	DOXAZOSIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	PUREPAC PHARMACEUTICAL	2/2/99	AP		10/18/00	PFIZER LABORATORIES	CARDURA TABLETS
75-536	DOXAZOSIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	TEVA PHARMACEUTICALS	12/28/98	AP		10/18/00	PFIZER LABORATORIES	CARDURA TABLETS
75-453	DOXASOZIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	ZENITH GOLDLINE	12/30/98	AP		10/18/00	PFIZER LABORATORIES	CARDURA
75-203	PROPAFENONE HYDROCHLORIDE TABLETS 150 MG 225 MG	WATSON LABORATORIES,	9/15/97	AP		10/24/00	KNOLL PHARMACEUTICAL CO.	RYTHMOL TABLETS